



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,478	02/25/2002	John L. Ricci	1065.36	4351
7590	11/19/2007		EXAMINER	
Melvin K. Silverman Suite 500 500 Est Cypress Creek Road Fort Lauderdale, FL 33309			BLANCO, JAVIER G	
			ART UNIT	PAPER NUMBER
			3774	
			MAIL DATE	DELIVERY MODE
			11/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/081,478	RICCI ET AL.	
	Examiner	Art Unit	
	Javier G. Blanco	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on August 23, 2007; September 19, 2007.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 37-43 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 37-43 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 23, 2007 has been entered.

Response to Amendment

2. Applicants' cancellation of claims 21-36 in the reply filed on August 23, 2007 is acknowledged.
3. Applicants' addition of claims 37-43 in the reply filed on August 23, 2007 is acknowledged.

4. Applicants' amendment of claim 37 in the reply filed on September 19, 2007 is acknowledged.

Terminal Disclaimer

5. The terminal disclaimer filed on August 23, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,419,491, US 6,454,569, and 09/784,284 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Priority

6. The instant application (i.e., 10/081,478; filed February 25, 2002):

- (i) Is a continuation-in-part of application 09/500,038 (filed February 8, 2000, now US 6,419,491),
- (ii) Which is continuation-in-part of application 08/996,244 (filed December 22, 1997, now abandoned),
- (iii) Which is continuation of application 08/639,712 (filed April 29, 1996, now abandoned),
- (iv) Which is continuation of application 08/390,805 (filed February 15, 1995, now abandoned),
- (v) Which is continuation of application 08/146,790 (filed November 2, 1993, now abandoned).

7. It is noted that the present Application is a **Continuation-In-Part** of US 6,419,491 B1 (Application Number 09/500,038).

The Applicants claim that Figures 20-23 of US 6,419,491 B1 (Application Number 09/500,038) show a planar substrate. However, the Examiner could not find support in the specification of US 6,419,491 B1 disclosing said SEM micrographs as showing a planar substrate. Further, the entire disclosure of US 6,419,491 B1 is drawn towards a cylindrical implant (i.e., dental implant). Additionally, the copy of Application Number 08/146,790 (copy submitted on December 18, 2006) does not comprise Drawings/Figures.

The subject matter (e.g., planar substrate) of independent claim 37 was not disclosed/described in US 6,419,491 B1. Further, the subject matter of claims 38-43 was not disclosed in US 6,419,491 B1 (or application 08/146,790). Therefore, the effective filing date for claims 37-43 is considered to be February 25, 2002.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 37 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Naiman et al. (US 5,607,607 A; previously cited by the Examiner in PTO-892). Naiman et al. '607 have an effective filing date of November 1st, 1993.

Referring to Figures 4A-4H, 5A-5F, 6A-6E, and 7-9, Naiman et al. disclose an implantable article (**Figure 7**: implant 46; **Figure 8**: hip prosthesis 54; **Figure 9**: dental implant 55) comprising micro-textured upper (Figure 7: grooves 44 and ridges 45 on upper surface; Figure 8: zone II; Figure 9: zone 61) and lower (Figure 7: grooves 48 and ridges inside cavity 47; Figure 8: zone I; Figure 9: zone 62) surfaces; said upper surface comprising grooves and ridges having a width and a height of about 2 to about 10 microns (see columns 9, 10, and 16), *for promoting soft tissue growth* (see columns 11-13); and said lower surface comprising grooves and ridges having a width and a height of about 8 to about 25 microns (see columns 9, 10, and 16), *for promoting bone tissue growth* (see columns 11-13); said article being substantially planar and biocompatible. Nayman et al.'s invention is applicable to various implants/prostheses or substrates

With regards to statements of intended use and other functional statements (e.g., for promoting soft tissue growth; for promoting bone tissue growth; etc.), they do not impose any structural limitations on the claims distinguishable over the device of Naiman et al., which is

capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

10. Claims 37-43 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Curtis et al. (US 5,833,641; cited in Applicants' IDS).

Curtis et al. disclose an article for the healing of wounds and repair of tissue defects (see Abstract) comprising a flexible membrane/sheet (see Figure 1; column 3, line 55 to column 4, line 2) having an upper and a lower surface (see column 5, lines 10-13), each surface defining a substrate formed of a biologically-acceptable biodegradable material adapted to be resorbed in use (see column 2, lines 31-34; column 3, lines 23-40), each substrate having thereon means capable of orienting cell growth comprising a microgeometry formed in said substrates (see column 4, lines 24-29), a microgeometry of an upper surface proportioned to a cell morphology of soft tissue cells and a microgeometry of a lower surface proportioned to a cell morphology of hard tissue cells (see column 5, lines 10-13; column 2, lines 35-46; column 3, line 55 to column 4, line 2; see entire document). Said membrane/sheet defines a width of between about 200 microns and about 500 microns (see column 3, lines 49-54). Said microgeometries comprise a pattern of

continuous grooves (see Figure 1; column 4, lines 30-67). Each of said microgeometries defining a dimension of about 1 micron to about 10 microns (see column 4, lines 35-44), depending on the targeted cell type (see column 4, lines 35-67).

With regards to statements of intended use and other functional statements (e.g., for promoting soft tissue growth; for promoting bone tissue growth; etc.), they do not impose any structural limitations on the claims distinguishable over the device of Curtis et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Response to Arguments

11. With regards to the rejection based on Naiman et al. (US 5,607,607 A; previously cited by the Examiner in PTO-892), Applicants’ arguments filed August 23, 2007 have been fully considered but they are not persuasive.

a. Naiman et al. have an effective filing date of November 1st, 1993.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 38-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naiman et al. (US 5,607,607 A; previously cited by the Examiner in PTO-892) in view of Curtis et al. (US 5,833,641; cited in Applicants' IDS).

Naiman et al. disclose the invention as claimed in claim 1. Although Naiman et al. disclose/suggest their invention as applicable to various implants/prostheses and substrates (e.g., sheets), they did not particularly disclose their article as bioabsorbable article having a thickness of between about 200 and about 500 microns, and a weight in a range of one to five grams/cm². However, this is already known in the art. For example:

Curtis et al. disclose a cell growth orienting means either integrally formed or provided on the surface of implants/prostheses (see column 2, lines 31-46), or as a bioabsorbable/biodegradable membrane/sheet/substrate (see Figure 1; column 2, lines 31-46; column 3, line 55 to column 4, line 2) wherein the biodegradable membrane/sheet/substrate defines a width of between about 200 microns and about 500 microns and a weight in a range of one to five grams/cm² (see column 3, lines 49-54; see column 4; see entire document) in order to provide a flexible nature to the membrane/sheet/substrate, allowing it to be inserted into wounds or wrapped around prostheses (see columns 2-4). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the

Art Unit: 3738

teaching of an implantable substrate having cell growth orienting means, a thickness of between about 200 and about 500 microns, and a weight in a range of one to five grams/cm², as taught by Curtis et al., with the implantable article (e.g., substrate) of Naiman et al., in order to provide a flexible nature to the membrane/sheet/substrate, allowing it to be inserted into wounds or wrapped around prostheses. Also, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

14. With regards to the 103(a) rejection based on Naiman et al. (US 5,607,607 A; previously cited by the Examiner in PTO-892) in view of Curtis et al. (US 5,833,641; cited in Applicants' IDS), Applicants' arguments filed August 23, 2007 have been fully considered but they are not persuasive.

a. The effective filing date of the subject matter of claims 38-43 is considered to be February 25, 2002. Therefore, Curtis et al. is Prior Art under 102(b).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for

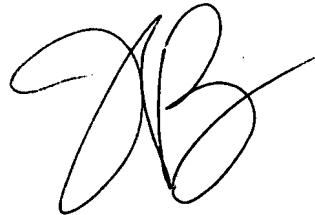
Art Unit: 3738

the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 14, 2007

Javier G. Blanco



David H. Willse
Primary Examiner